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EXAMINER	
LONG, SCOTT	

ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/783,994	REINHERZ ET AL.	
	Examiner	Art Unit	
	Scott D. Long	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-39* is/are pending in the application.

4a) Of the above claim(s) *9 and 13-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 9-12, and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/20/2007 has been entered.

Claim Status

Claims 1-7 and 10 are amended. Claim 8 is cancelled. Claim 39 is newly submitted. Claims 9 and 13-38 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. Claims 1-7, 10-12, and 39 are under current examination.

Priority

This application claims benefit from PCT/US02/08288 (filed 14 March 2002) which claims benefit from provisional US Application 60/314,046 (filed 21 Aug 2001) and from provisional US Application 60/322,993 (filed 18 Sept 2001). The instant application has been granted the benefit date, 18 September 2001, from the application 60/322,993.

Response to Arguments - Claim Rejections 35 USC § 112

Applicant's claim amendments and arguments with regard to the rejection of claims 1-3 under 35 USC 112, 1st paragraph, New Matter/Written Description (page 14, REMARKS, received 6/20/2007) have been fully considered, and are found to be persuasive. The applicant has amended the instant claims so as to match the claim language found in the specification.

Therefore, the examiner withdraws the rejection of claims 1-3 under 35 USC 112, 1st paragraph, New Matter/Written Description.

Applicant's claim amendments and arguments with regard to the rejection of claim 7 under 35 USC 112, 1st paragraph, Written Description (pages 11-12, REMARKS, received 6/20/2007) have been fully considered, but are unpersuasive. The claim remains rejected for the reasons of record and the following comments.

The applicant is essentially arguing that the addition of the claim language which further limits the isolated nucleic acid to encode a polypeptide that reduces NF-kB sensitive reporter activity in Cos cells, has created enough limitations on the genus of nucleic acids, so that the specification adequately supports possession of the claimed genus of isolated nucleic acids.

Contrary to the applicant's assertion, claiming sequences based on functionality is not sufficient to demonstrate support for a genus of indeterminate sequences. MPEP

§ 2163, states "[A] biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, ***even when accompanied by a method of obtaining the claimed sequence."*** Coupling MPEP 2163 with the examiner's prior arguments (Actions filed 9/19/2006 and 3/26/2007), which indicated that there will be numerous unknown sequences capable of being identified by hybridization screening, leads the examiner to the conclusion that the a skilled artisan would not recognize that the applicant was in possession of the claimed invention (genus) commensurate to its scope at the time the application was filed.

Therefore, the examiner maintains the rejection of claim 7 under 35 USC 112, 1st paragraph (Written Description).

Applicant's claim amendments and arguments with regard to the rejection of claim 7 under 35 USC 112, 1st paragraph, Enablement (page 12, REMARKS, received 6/20/2007) have been fully considered, but are unpersuasive. The claim remains rejected for the reasons of record and the following comments.

The applicant is essentially arguing that the addition of the claim language which further limits the isolated nucleic acid to encode a polypeptide that reduces NF-kB sensitive reporter activity in Cos cells, has created enough limitations on the genus of nucleic acids, so that the specification has now enabled the claimed genus of isolated

nucleic acids. While narrowing the scope of the genus comprising nucleic acids identified by stringent hybridization to SEQ ID NO:1, the complement of SEQ ID NO:1, or nucleic acids that encode SEQ ID NO:2, the applicant has not overcome the uncertainty encountered when isolating nucleic acids by hybridization methods and overcome the lack of guidance and working examples. The hybridization conditions provided in the specification do not guarantee that undue experimentation would not be required by the skilled artisan to generate the claimed genus of isolated nucleic acids. Therefore, the examiner has submitted a modified form of his earlier rejection.

Claims 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The Court in *Wands* states: "Enablement is not precluded by the necessity for some 'experimentation.'" Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working

examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

Nature of the Invention

The full scope of the claimed invention encompasses an enormous number of nucleic acids which could hybridize with SEQ ID NO:1, the complement of SEQ ID NO:1, or a nucleic acid sequence that encodes SEQ ID NO:2. The size of these hybridizing nucleic acids might be small, or equal in size to full-length SEQ ID NO:1, or larger than SEQ ID NO:1. The nucleic acids might also encompass very large nucleic acids that hybridize under highly stringent conditions only over a short range near one end of both sequences. In this case, there would be a very low level of homology between the two sequences, despite high stringency hybridization.

With respect to claims limiting a polynucleotide by hybridization conditions, even under relatively high stringent conditions, the claimed nucleotide sequence could hybridize to a genus of polynucleotides that are similar, but not identical to the recited polynucleotides. The limitation by hybridization is obviously generic to a considerable number of nucleotides varying in the length of the nucleic acids, the degree of homologies among the sequences, and the biological activities of the encoded polypeptides, which may be involved in more than merely the function of IkBNS. This

genus also embraces sub-sequences that are unknown and include unsequenced polynucleotides, whose function is yet to be determined.

Working Examples and Guidance Provided

The instant application suggests that hybridizing nucleic acids might be "greater than about 75 percent, more preferably greater than about 80 percent, and even more preferably greater than about 90 percent, identical to a nucleotide sequence...consisting of SEQ ID NO:1" (Spec., page 3, lines 27-29). Other than these preferred homologies, there is no guidance given for nucleic acids that meet the limitations of Claim 7, but are not probes as in Claim 8. Neither are there working examples of nucleic acids that have been isolated through the stringent hybridization method. Furthermore, there are no examples of nucleic acid sequences described in the specification that conform to the limitations of claim 7.

State of the Art and Analysis of the Issues

A skilled artisan would not know how to make a nucleic acid which corresponds to the large number of species of nucleic acid encompassed by Claim 7. Some of the nucleic acids that fit within the genus of Claim 7 would not be homologues of SEQ ID NO:1. In fact, despite hybridizing under high stringency conditions, these molecules would be structurally unrelated to SEQ ID NO:1-2 and yet encode a polypeptide that reduces NF-kB sensitive reporter activity in Cos cells. Sequences which fit into this class of unrelated molecules would require further research in order for an artisan to

learn how to use them. Furthermore, the artisan would have no reason to make such sequences.

Wolcott (CLINICAL MICROBIOLOGY REVIEWS, Oct. 1992, p. 370-386) teaches "hybridization...is subject to...nonspecific background interference" (page 372, column 1) and "hybridization studies...produced...false-positive reactions" (page 371, column 2). Walcott further teaches "short probes...are subject to more nonspecific hybridizations, are limited in specificity, and are more difficult to label....Long probes hybridize more stably than short probes at high temperatures and low salt concentrations (low stringency)." (page 371, column 2). Gress et al. (*Mammalian Genome 3:* 609-619, 1992) teach, "complex probes usually generate a high amount of background and unspecific hybridization." (page 610, column 1). The teachings of Wolcott and Gress et al. cast doubt on the homology of the sequences derived through hybridization methods. If sequences that hybridize under stringent conditions are not homologous or functionally related to those sequences of the genus of claim 7, then there is surely difficulty for the artisan to make and/or use these sequences. Or if the amount of relatedness of the hybridizing sequence to SEQ ID NO:1 only comprises a single domain (perhaps one that reduces NF-kB sensitive reporter activity in Cos cells), then the artisan would likewise encounter difficulty in using these sequences and would be required to perform further investigation to find a utility for these discovered sequences.

Therefore, the quantity of experimentation required to make and/or use the invention, as claimed, is insufficient to enable the invention.

Response to Arguments - Claim Rejections 35 USC § 102

Applicant's claim amendments and arguments, see page 12-13, REMARKS, received 6/20/2007 have been fully considered, but are unpersuasive.

The applicant argues that there is no anticipation by Lamerdin et al (GenBank Accession No. AD000864. 22 March 1997) to reject claims 1-2 and 4-5 under 35 U.S.C. 102(b). The examiner maintains that the arguments of the applicant are insufficient to overcome the rejection of claims 1-2 and 4-5 for the reasons of record and comments below.

The applicant has amended claim 1, to remove option 1-v, directed to "an isolated nucleic acid molecule consisting of a nucleic acid sequence selected from...a nucleic acid that encodes SEQ ID NO:2" and amended the scope of claim 1 options i-iv to further encompass limitations "wherein said isolated nucleic molecule encodes a polypeptide that reduces NF-kB sensitive reporter activity in Cos cells." Presumably, all of the isolated nucleotides that are described by claim 1 options i-iv encode polypeptides that reduce NF-kB sensitive reporter activity in Cos cells.

The examiner reasserts an earlier argument, the sequence taught by Lamerdin et al. teach an isolated nucleic acid molecule consisting of a nucleic acid sequence selected from...a portion of SEQ ID NO:1 which is greater than 500 nucleotides in length. Lamerdin et al. teach also teach a portion of the complement of SEQ ID NO:1 which is greater than 500 nucleotides in length. Because the Office presumes the specification to be true and the applicant asserts that all the nucleic acids encompassed

by claim 1, options i-iv, also encode a polypeptide "that reduces NF-kB sensitive reporter activity in Cos cells", the examiner asserts that the sequences that are taught by Lamerdin which meet the limitations of claim 1 options I-iv inherently encode a polypeptide that reduces NF-kB sensitive reporter activity in Cos cells. Therefore, claims 1-2 remain rejected.

Regarding claims 4-5, the examiner reasserts arguments from earlier actions that "the Lamerdin et al. sequence teaches all of the 15000 bases of SEQ ID NO:1....Many molecules can encode SEQ ID NO:2. For example, a cDNA molecule can encode SEQ ID NO:2. However, the instant Specification (page 2, lines 20-27) indicates that SEQ ID NO:1 can encode SEQ ID NO:2. Since SEQ ID NO:1 contains introns and encodes SEQ ID NO:2, the GenBank sequence AD000864 which comprises SEQ ID NO:1 that is capable of encoding SEQ ID NO:2" (page 11, Office Action, mailed 9/19/2007). The examiner reasserts that the sequence taught by Lamerdin et al. teaches an isolated nucleic acid molecule consisting of a nucleic acid sequence selected from...a nucleic acid that encodes SEQ ID NO:2. IkBNS (SEQ ID NO:2) is encoded by SEQ ID NO:1 and IkBNS has been demonstrated to be a polypeptide that reduces NF-kB sensitive reporter activity in Cos cells. Therefore, Lamerdin et al. teaches an isolated nucleic acid sequence that inherently reduces NF-kB sensitive reporter activity in Cos cells.

In addition, the applicant disagrees with the examiner's analysis and explains that Lamerdin et al. (GenBank Accession No. AD000864) discloses a 39,146 base, single-stranded DNA sequence which encodes APLP1. The applicant argues that the Lamerdin sequence does not comprise SEQ ID NO:1, but instead teaches the reverse

complement of SEQ ID NO:1. GenBank DNA sequence submissions only include a single strand. Nevertheless, the reverse complement of a GenBank DNA sequence is inherent in the sequence submitted. Such a sequence teaches limitations 1iii-iv. It is for this reason that the examiner originally rejected claim 1 and maintains his rejection of claim 1.

The examiner agrees with the applicant that Lamerdin et al. sequence (GenBank Accession No. AD000864) does not teach to an isolated nucleic acid molecule consisting of a nucleic acid sequence SEQ ID NO:1 or the complement thereof.

Nevertheless, the rejection of claims 1-2 and 4-5 under 35 USC 102(b) is maintained.

Applicant's claim amendments and arguments, see page 14, REMARKS, received 6/20/2007 have been fully considered, and are found persuasive.

The applicant argues that there is no anticipation by Neto et al (PNAS 97(7): 3491-34-96 (2000)) to reject claims 7-8 under 35 U.S.C. 102(b). The examiner accepts the applicant's arguments that the teachings of Neto et al. are sufficient to overcome the rejection of claim 7, "because the 182 nucleotide DNA sequence taught by Neto et al. would only hybridize to an intronic sequence of SEQ ID NO:1 and thus cannot encode a polypeptide that reduces NF-kB sensitive reporter activity in Cos cells" (REMARKS, page 14). The cancellation of claim 8 makes the rejection moot. Therefore, the examiner withdraws the rejection of claims 7-8 under 35 USC 102.

Response to Arguments - Claim Rejections 35 USC § 103

Applicant's claim amendments and arguments, see pages 13-14, REMARKS, received 6/20/2007 have been fully considered, but are unpersuasive.

The applicant argues that the teachings of Lamerdin et al (GenBank Accession No. AD000864. 22 March 1997) do not meet the limitations of claims 1-6 under 35 U.S.C. 103(a). However, the examiner maintains that the arguments of the applicant are insufficient to overcome the rejection of claims 1-6 for the reasons of record and comments below.

The applicant particularly asserts that Lamerdin et al. do not teach an isolated nucleic acid that encodes a polypeptide that reduces NF-kB sensitive reporter activity in Cos cells.

As described above, in the discussion of Lamerdin et al. under the 35 USC 102 section, Lamerdin teaches the limitations of claims 1-2 and 4-5. Since the Lamerdin sequence meets the sequence limitations of claims 1-2 and 4-5 and intrinsically contains sequences that encode a polypeptide that reduces NF-kB sensitive reporter activity in Cos cells, the examiner maintains that these teachings are obvious over these claims.

Claims 3 and 6 are directed to the further limitation that the nucleic acid of claims 1 and 4 are RNA. Any skilled artisan using the sequence taught by Lamerdin et al. would be able to deduce the corresponding RNA of the DNA sequence SEQ ID NO:1 and the RNA that encodes the protein sequence of SEQ ID NO:2.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to utilize a portion of the sequence of GenBank Acc# AD000864 that contains all of the exons of a gene. The specification of the instant application does not specify why the exact size of 15,000 bases was selected for the invention of SEQ ID NO:1. Therefore, any sequence that contains all of the gene of interest would be equivalent.

The person of ordinary skill in the art would have been motivated to make those modifications because a genomic DNA sequence that contains all of the coding sequence of a given gene.

The skilled artisan would have had a reasonable expectation of success in utilizing the nucleic acid sequence of Lamerdin et al. in place of the nucleic acid sequence of SEQ ID NO:1 or in place of the nucleic acid sequence which encodes SEQ ID NO:2, because the Lamerdin sequence can be substituted for any functions that the sequences of the instant application are put to use.

Therefore the isolated nucleic acid as taught by Lamerdin et al. would have been *prima facie* obvious over the isolated nucleic acid of the instant application.

Applicant's claim amendments and arguments with regard to the rejection of claims 10-12 under 35 USC 103 (pages 13-14, REMARKS, received 6/20/2007) have been fully considered, but are unpersuasive.

As described above, in both the 102 and 103 sections, the examiner reasserts that the Lamerdin et al. sequence does indeed satisfy the limitations of claims 1 and 4. Essentially, the vectors of claims 10-11 comprise the nucleic acids of claims 1 or 4. The cell of claim 12 comprises the vector of claim 11. Because there is sufficient motivation to combine the vectors and cells of Liu et al. with the Lamerdin sequence and the examiner holds that the Lamerdin sequence meets the limitations of the isolated nucleic acids sequences described in claim 10, the rejection of claims 10-12 under 35 USC 103(a) is maintained.

NEW GROUNDS REJECTIONS

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 7 and 10-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER REJECTION.**

The methodology for determining adequacy of Written Description to convey that applicant was in possession of the claimed invention includes determining whether the application describes an actual reduction to practice, determining whether the invention is complete as evidenced by drawings or determining whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention (*Guidelines for Examination of Patent Applications under 35 USC § 112, p 1 "Written Description" Requirement;* (Federal Register/Vol 66. No. 4, Friday, January 5, 2001; II Methodology for Determining Adequacy of Written Description (3.)).

Claims 1, 7, and 10 are broadly drawn, such that they apply to a genus of isolated nucleic acids that are complements of SEQ ID NO:1 (or portions thereof) and encode a polypeptide that reduces NF-kB sensitive reporter activity in Cos cells.

There are no working examples provided in the instant application that demonstrate an isolated nucleotide sequence that is complementary to any portion of SEQ ID NO:1 and also encodes a polypeptide that reduces NF-kB sensitive reporter activity in Cos cells. The specification inherently teaches the complement of SEQ ID NO:1. The specification also teaches that SEQ ID NO:2, which is encoded by SEQ ID NO:1, is a polypeptide that reduces NF-kB sensitive reporter activity in Cos cells. However, while the specification supports each of these limitations separately, it does not support the limitations together.

The Revised Interim Guideline for Examination of Patent Applications under 35 USC § 112, p1 "Written Description" Requirement (Federal Register/ Vol 66. No 4, Friday January 5, 2001) states "THE CLAIMED INVENTION AS A WHOLE MAY NOT BE ADEQUATELY DESCRIBED IF THE CLAIMS REQUIRE AN ESSENTIAL OR CRITICAL ELEMENT WHICH IS NOT ADEQUATELY DESCRIBED IN THE SPECIFICATION AND WHICH IS NOT CONVENTIONAL IN THE ART" (column 3, page 71434), "WHEN THERE IS SUBSTANTIAL VARIATION WITHIN THE GENUS, ONE MUST DESCRIBE A SUFFICIENT VARIETY OF SPECIES TO REFLECT THE VARIATION WITHIN THE GENUS", "IN AN UNPREDICTABLE ART, ADEQUATE WRITTEN DESCRIPTION OF A GENUS WHICH EMBRACES WIDELY VARIANT SPECIES CANNOT BE ACHIEVED BY DISCLOSING ONLY ONE SPECIES WITHIN THE GENUS" (column 2, page 71436, emphasis added).

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "APPLICANT MUST CONVEY WITH REASONABLE CLARITY TO THOSE SKILLED IN THE ART THAT, AS OF THE FILING DATE SOUGHT, HE OR SHE WAS IN POSSESSION OF THE INVENTION. THE INVENTION IS, FOR PURPOSES OF THE 'WRITTEN DESCRIPTION' INQUIRY, *WHATEVER IS NOW CLAIMED*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize the [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

The disclosure is not sufficient to show that a skilled artisan would recognize that the applicant was in possession of the claimed invention (genus) commensurate to its scope at the time the application was filed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 39 is rejected under 35 U.S.C. 102(b) as being anticipated by Lamerdin et al (GenBank Accession No. AD000864. 22 March 1997).

Claim 39 is directed to "an isolated nucleic acid molecule consisting of a nucleic acid sequence that encodes SEQ ID NO:2."

The Lamerdin et al. sequence teaches all of the 15000 bases of SEQ ID NO:1. See also FASTA alignment of SEQ ID NO:1 and GenBank Acc# AD000864 for comparison of sequences. The claim language of claim 39 contains closed language ("consisting of") followed by open language ("encodes"). Many molecules can encode SEQ ID NO:2. For example, a cDNA molecule can encode SEQ ID NO:2. However, the instant Specification (page 2, lines 20-27) indicates that SEQ ID NO:1 can encode SEQ ID NO:2. Since SEQ ID NO:1 contains introns and encodes SEQ ID NO:2, the

GenBank sequence AD000864 which comprises SEQ ID NO:1 that is capable of encoding SEQ ID NO:2 and therefore meets the limitations of claim 39. Presumably, all of the isolated nucleotides that are described by claim 39 encode polypeptides that reduce NF-kB sensitive reporter activity in Cos cells. The examiner asserts that the sequences that are taught by Lamerdin which meet the sequence limitations of claim 39 inherently encode a polypeptide that reduces NF-kB sensitive reporter activity in Cos cells.

Accordingly, Lamerdin et al. anticipated the instant claims.

Conclusion

No claims are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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